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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Takeya Abe

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Robert G Mukai
Burns Doane Swecker & Mathis
PO Box 1404
Alexandria, VA 22313-1404

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

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1652

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/936,514	Applicant(s) ABE ET AL.	
	Examiner CHRISTIAN L. FRONDA	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,11-16 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,11-16 and 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The finality of the previous Office Action has been withdrawn. New rejections and new grounds of rejection are presented in the instant Office Action.
2. Claims 1, 3, 9, 11-16, and 25-31 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 9, 11-16, and 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase “microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body” which renders the claim vague and infinite. The metes and bounds of the claim are uncertain. The specification discloses bacterial strains such as MT-10827 (FERM BP-5785) which is not a fungus, but is instead an *E.coli* host cell transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352). It is unclear as to what is being encompassed by the phrase “microorganism fungus body”. Furthermore, the meaning of the phrase “processed product of the microorganism fungus body” is uncertain since it is unclear if such “processed product” still contains the nitrile hydratase of the “microorganism fungus body”. Dependent claims 3, 9, 11-16, and 25-31 are also included in the rejection because they do not correct the defect of claim 1. Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 9, 11-16, and 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The arguments filed 01/22/2008 have been fully considered but they are not persuasive for the reasons of record as further explained.

Applicants are directed toward the USPTO Written Description Training Materials made available to the public on 04/11/2008 for information regarding examination of patent claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph.

According to MPEP 2163, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed.Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

The method steps reciting the products must comply with the written description requirement. The claims are genus claims directed toward a method using a genus of nitrile hydratases of any amino acid sequence and structure from any “microorganism fungus body” and a genus of any “processed product of the microorganism fungus body”.

The scope of each genus includes many members such as nitrile hydratase enzymes with widely differing structural, chemical, and physical characteristics. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exists. Recitation of the name “nitrile hydratase” and its source as a “microorganism fungus body” and “processed product of the microorganism fungus body” do not define any structural features and amino acid sequences commonly possessed by the genus. The specification does

not describe and define any structural features and amino acid sequences commonly possessed by each genus. There is no art-recognized correlation between any structure of a nitrile hydratase and any “processed product of the microorganism fungus body”. Those of ordinary skill in the art would not be able to identify without further testing what specific “processed product of the microorganism fungus body” would have a nitrile hydratase that can be used in the claimed method.

As stated in the previous Office Actions, the specification discloses a MT-10827 (FERM BP-5785) which is not a not a fungus, but is instead an *E.coli* host cell transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352), and its use in converting acylonitrile to its corresponding amide acrylamide.

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional nitrile hydratases, “microorganism fungus body”, and “processed product of the microorganism fungus body” encompassed by the claims. As such the disclosure of the above mentioned *E.coli* MT-10827 (FERM BP-5785) is insufficient to be representative of the attributes and features common to all the members of each claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each claimed genus.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the invention recited in claims 1, 3, 9, 11-16, and 25-31.

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3, 9, 11-16, 25-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oriel et al. (WO 99/55719; reference of record) in view of Chen. (J Biol Chem. 1967 Jan 25;242(2):173-81; reference of record). The reference teachings and rejection have been stated in the previous Office Actions. The arguments filed 01/22/2008 have been fully considered but they are not persuasive for the reasons of record as further explained.

According to MPEP 2143:

“Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.”

As stated in the previous Office Actions, Oriel et al. teach a process where BR449 cells are contacted with acrylonitrile to produce a solution containing acrylamide, the said BR449 cells are separated from the reaction mixture, the said acrylamide solution is treated with activated charcoal (an activated carbon), to remove contaminants and the acrylamide is concentrated or precipitated by distillation or evaporation under reduced pressure (see entire publication especially p. 17, line 17 to p.18, line 24). Oriel et al. further teach that other

unsaturated aliphatic nitrile compounds such as crotononitrile and methacrylonitrile that can be converted using the nitrile hydratase of BR449 (see p. 36, lines 27-28).

The reference of Oriel et al. clearly shows that activated charcoal, which is known in the art to be treated with acid in order to activate the charcoal, was used to purify acrylamide from the reaction mixture. Therefore, one of ordinary skill in the art at the time the invention was made would recognize and predict that nitrile compounds containing an unsaturated bond are stable in acidic conditions. Furthermore, the process of Oriel et al. would inherently remove impurities including proteins since the process involves not only contacting the solution with activated carbon but also includes steps for concentrating or precipitating by distillation or evaporation the amide solution, thereby removing contaminating proteins.

As stated in the previous Office Actions, Chen teach process steps for removing lipid impurities by acid-charcoal treatment, using an acidic range of pH 3 to pH 7 at 2°C where the charcoal is made from wood (see entire publication, especially Figs. 1-4 and pp. 174-177). The reference of Chen clearly shows that acid-charcoal treatment, using an acidic range of pH 3 to pH 7 at 2°C, is used for removing lipid impurities, which are expected to be contained within the recited “microorganism fungus body”, and “processed product of the microorganism fungus body”. Therefore, one of ordinary skill in the art at the time the invention was made would recognize and predict that in order to remove such lipid impurities from the reaction mixture, acid-charcoal treatment using an acidic range of pH 3 to pH 7 at 2°C is required. Furthermore, one of ordinary skill in the art at the time the invention was made would try to optimize the pH and temperature of the reaction mixture in order to obtain the highest, purified yield of the amide compound from the reaction mixture.

The examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the amended claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000. CLF

/Tekchand Saidha/
Primary Examiner, Art Unit 1652